



# Assessments of Mid-day Fogging with a Novel Scleral Lens Filling Solution

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## INTRODUCTION

Mid-day fogging in scleral lens wear is a disruptive problem affecting many wearers, necessitating the removal of lenses and refilling of solution, often repeatedly throughout the day. This fogging phenomenon likely has multiple causes, one of which is the result of the sloughing of corneal epithelial cells trapped under the scleral lens. A filling solution with an ionic composition and pH to mirror natural tears may help minimize corneal cell sloughing and build up when compared to saline formulations that are used with scleral lenses currently.

## METHODS

Scleral lens wearers with reports of mid-day fogging were enrolled in a 3 visit, 1 week study, to compare their symptoms and fogging when using their habitual filling solution to their experiences when using a solution consisting of calcium, magnesium, potassium and sodium ions, with a pH matching the ocular surface. The initial round of 11 subjects used the solution as it was prepared by a local compounding pharmacy. A second round was conducted using same solution as prepared by a cGMP compliant Blow-Fill-Seal manufacturer. The initial subjects were invited to repeat the study with the commercial packaging, and additional midday scleral lens wearers were enrolled with a target of completing 30 subjects in the study. At the initial visit, subjects completed OSDI and visual analog surveys of symptoms, were examined for fogging with their habitual solution, and had an ocular health assessment without lenses. Subjects then filled their habitual lenses with the test filling solution and were examined. Subjects returned approximately 4 hours later for an assessment of ocular health and fogging. Solution was dispensed for use until a follow up visit 5-9 days later. Subjects were examined for fogging, ocular health, and completed the surveys again at this final visit.

## RESULTS

The results of the initial round of the study found a statistically significant improvement of  $13.33 \pm 14.26$  units on mean OSDI scores ( $p=0.024$ ) when comparing the test solution to the habitual saline solution. Comparisons with visual analog scale surveys also found a mean decrease of  $3.0 \pm 9.3$  units in symptoms of Grittiness/Foreign Body Sensation ( $p=0.026$ ), a mean decrease of  $17.9 \pm 18.6$  units in symptoms of dryness ( $p=0.0008$ ), and a mean decrease of  $4.1 \pm 12.9$  ( $p= 0.004$ ) Blurry/Fluctuating Vision. Examiner grading of fogging of 20 eyes found improvements in the amount of fogging for 7 subjects, no change for 12 eyes, and an increase in fogging for 1 eye when comparing assessments with the habitual solution to those done after 5-9 days of test solution use.

## CONCLUSIONS

Filling a scleral lens with a solution that contains the same components of the tears and matches the pH of the ocular surface shows improvements in symptoms associated with mid-day fogging of scleral lenses.

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Figure 1. Patient #1 with habitual solution



Figure 2. Patient #1 with test solution